

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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IN RE FOREST LABORATORIES :
SECURITIES LITIGATION : 05 Civ. 2827 (RMB)
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This Document Relates to: All Actions :
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ORDER

I. Introduction

This is a consolidated securities class action against Forest Laboratories, Inc. ("Forest" or the "Company"), Howard Solomon, Forest's Chairman and Chief Executive Officer ("Solomon"), John E. Eggers, Forest's Vice President and Chief Financial Officer ("Eggers"), Kenneth E. Goodman, Forest's President and Chief Operating Officer ("Goodman"), Elaine Hochberg, Forest's Senior Vice President for Marketing ("Hochberg"), Lawrence S. Olanoff, Forest's Executive Vice President for Scientific Affairs ("Olanoff"), Mary E. Prehn, Forest's Vice President of Licensing and Corporate Development ("Prehn"), Raymond Stafford, Forest's Executive Vice President for Global Marketing ("Stafford"), and Charles E. Triano, Forest's Vice President for Investor Relations ("Triano").¹

Plaintiffs allege that Defendants violated the federal securities laws, particularly Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b) ("Section 10(b)" or "§10(b)"), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) ("Section 20(a)"), (see Amended Complaint, dated August 12, 2005 ("Amended Complaint")), claiming, *inter alia*, that Defendants "misled investors . . . regarding the safety and efficacy of Forest's pharmaceutical products, as well as the Company's promotional practices and clinical research." (Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Amended Complaint, dated December 9, 2005 ("Pl. Mem."), at 1.) At the core of Plaintiffs'

¹ Solomon, Eggers, Goodman, Hochberg, Olanoff, Prehn, Stafford, and Triano are referred to collectively as the "Individual Defendants." The Individual Defendants together with Forest are referred to as "Defendants."

Amended Complaint is the charge that Defendants “published clinical studies purportedly showing that a Forest anti-depressant, Celexa, was safe and efficacious for the treatment of depression in children and adolescents, but concealed concurrent studies demonstrating not only that Celexa was no more effective than a placebo, but that it actually increased the risk that pediatric patients would commit suicide.” (Pl. Mem. at 1.)

On November 7, 2005, Defendants moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) arguing that the Amended Complaint (A) does not properly allege false or misleading statements because it fails to “plead facts from specific documentary or personal sources”; (B) fails to plead “particularized circumstantial evidence that could support the strong inference of scienter demanded by Rule 9(b) and the PSLRA,” “omit[s] the information necessary to assess whether [the Individual Defendants’] class-period [stock] transactions were unusual enough to create a strong inference of scienter,” and fails to implicate each of the Individual Defendants in wrongdoing; (C) fails “to allege facts supporting the ‘loss causation’ element of a section 10(b) claim”; and (D) “these deficiencies require dismissal of . . . [Plaintiffs’] related claims under sections 20(a) and Section 20A of the Exchange Act.” (See Defendants’ Memorandum of Law in Support of Defendants’ Motion to Dismiss the Amended Complaint, dated November 7, 2005 (“Def. Mem.”), at 2-3.) On or about December 9, 2005, Plaintiffs submitted an opposition contending that (A) “defendants may not publish favorable information and at the same time suppress unfavorable information”; (B) “defendants were provided with unpublished, unfavorable . . . studies during the Class Period but suppressed them” and “defendants’ insider [stock] sales of over \$300 million during the Class Period [leave] no doubt that a strong inference of scienter has been pleaded”; (C) Forest Labs’ stock price declines “occurred when the false and misleading nature of defendants’ earlier statements finally came to light, directly damaging investors who purchased Forest stock unaware of defendants’ misrepresentations”; and (D) Plaintiffs have properly pleaded violations of Section 20(a)

of the Exchange Act. (See Pl. Mem. at 1-3.) Defendants filed a reply on December 27, 2005. (See Defendants' Reply Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint, dated December 27, 2005 ("Def. Reply").) The Court held oral argument on July 18, 2006.² (See Transcript of Oral Argument, dated July 18, 2006.)

For the reasons set forth below, Defendants' motion to dismiss is granted in part and denied in part.

II. Background

The following allegations are set forth in the Amended Complaint and are accepted as true for the purposes of this motion. Cooper v. Parksy, 140 F. 3d 433, 440 (2d Cir. 1998).

Forest is a pharmaceutical company that sells drugs through, among other things, a sales force that promotes its drugs to physicians. (See Amended Complaint ¶ 1.) Plaintiffs claim that between August 15, 2002 and September 1, 2004 (the "Class Period"), Forest made a number of false and misleading statements regarding the safety and efficacy of its pharmaceutical products, (Pl. Mem. at 1), including (1) Forest's characterization of two anti-depression drugs, Celexa and Lexapro, as being different from one another; (2) concealment of unfavorable studies regarding the use of Celexa and Lexapro for the treatment of adolescent depression; (3) promotion by Forest's sales force of Celexa and Lexapro for "off-label" use in treating adolescent depression³; and (4) misleading statements about the timing and chances of success of Forest's application with the United States Food and Drug Administration ("FDA") for approval of its Alzheimer's drug, Namenda, in the treatment of mild to

² At the oral argument, counsel addressed, inter alia, a recent decision by United States District Court Judge Joseph J. Farnan in Forest Laboratories, Inc. v. IVAX Pharmaceuticals, Inc., No. 03 Civ. 891 (D. Del.). (See Transcript of Oral Argument, dated July 18, 2006.)

³ According to the Amended Complaint, the FDA "approves drugs only for specified, limited uses. Drug companies are only permitted to promote or market drug products for those specified, limited uses. However, physicians are permitted to prescribe a drug for any use they think beneficial for the patient as long as the drug has been approved by the FDA for any use. This prescription practice is known as 'off-label use' of a drug." (Amended Complaint ¶ 3; see also Def. Mem. at 5.)

moderate cases of the disease. (See Def. Mem. at 11, 12, 15, 17; Pl. Mem. at 27-28.)

(1) Characterization of Celexa/Lexapro

According to the Amended Complaint, “Forest scored a great success” in August 1998 when it launched Celexa, “a patented selective serotonin reuptake inhibitor (“SSRI”) drug which Forest license[d] from a Danish company (Lundbeck) for sale in the United States,” to treat depression. (Amended Complaint ¶ 1.) Lexapro “contained the same active ingredient as Celexa and therefore would be essentially the same as Celexa, but with sufficient claimed differences to justify the follow-on drug being granted a patent and its own period of market exclusivity extending for years beyond when Celexa would ‘go generic.’” (Amended Complaint ¶¶ 1, 59.) Plaintiffs contend that the following public statements made by Forest officers were false and misleading:

- Lexapro has “greater effect, faster speed of action and fewer side effects” than Celexa in a Dow Jones News Service article dated January 14, 2002. (Amended Complaint ¶ 53.)
- “While Celexa, which Forest first introduced in 1998, is still the fastest growing SSRI in the market and has proven effective in the treatment of major depression, Lexapro’s combination of tolerability and powerful efficacy, resulting in many patients experiencing relief early in their treatment, may make it highly desirable for the treatment of major depression” in an announcement by Forest dated August 15, 2002. (Declaration of Daniel Signorelli, Esq. in Support of Defendants’ Motion to Dismiss Amended Complaint, dated November 7, 2005 (“Signorelli Aff.”), Ex. 3.)
- Lexapro “is quite different So, for patients we will have a drug that is more efficacious, acts more quickly, has lower side effects and has less drug interaction than [Celexa]” in a television interview with Defendant Goodman on September 5, 2002. (Amended Complaint ¶ 62.)

Plaintiffs contend that Forest knew of a study conducted by the Danish Medicines Agency in August of 2002, prior to the introduction of Lexapro, which found that “Cipralext (Lexapro), had no clear advantages to its top-selling predecessor [Celexa],” and Forest knew that Swedish and Australian scientists “concluded in a study published in [2004’s] edition of the medical journal Psychotherapy and Psychosomatics” that Lexapro was not more effective than Celexa. (Amended Complaint ¶¶ 41-

42.) On or about June 13, 2005, “the Centers for Medicare and Medicaid Services (CMS), a federal agency within the U.S. Department of Health and Human Services, reported that henceforth Medicare formularies need only include Celexa ... or Lexapro ... because these are essentially identical.” (Amended Complaint ¶ 135.)

(2) Concealment of Unfavorable Celexa/Lexapro Studies

Plaintiffs contend that “Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest’s knowledge, consent and input” which “had demonstrated that there was no pre-adult efficacy from the drug and . . . that there were significant adverse side-effects, including increased suicidality [(the ‘Lundbeck Study’)].” (Amended Complaint ¶ 13.) Plaintiffs also contend that, while Lundbeck’s European antidepressant “included a warning that patients should be monitored for suicide risks,” there was “no warning with Lundbeck’s antidepressants sold on the American market by . . . Forest.” (Amended Complaint ¶ 61.)

Plaintiffs contend that Forest’s failure to disclose the Lundbeck Study and to include a warning about the risk of suicide made the following statements, among others, false and misleading:

- “Celexa was shown to reduce symptoms of depression in adolescents and children with major depressive disorder to a significantly greater extent than placebo in a randomized, double-blind, placebo-controlled, flexible-dose study of 174 pediatric patients (83 children and 91 adolescents) The study also showed that Celexa was well tolerated” according to a press release issued by Forest dated December 31, 2001 (Amended Complaint ¶ 53.)
- In May 2002, “Forest arranged for the pediatric Celexa study to be publicly presented . . . at the Annual Meeting of the American Psychiatric Association in Philadelphia.” The study concluded that “[i]n this population of children and adolescents, treatment with citalopram reduced depressive symptoms to a significantly greater extent than placebo treatment and was well tolerated.” (Amended Complaint ¶ 57.)
- Celexa and Lexapro “may improve symptoms of major depressive disorder with minimal side effects in children and adolescents, according to two studies” discussed in a December 1, 2002 article in Clinical Psychiatry News. (Amended Complaint ¶ 66.)

On April 23, 2004, a British medical journal, The Lancet, published an article that reviewed the Lundbeck Study. (See Amended Complaint ¶ 114 (“Celexa, in two unpublished trials involving 422 children, didn’t reduce depression symptoms enough to show a benefit and raised the risk of suicide attempts and side effects, the researcher said.”).) On or about June 24, 2004, Forest announced that childhood and adolescent “patients receiving Lexapro did not demonstrate statistically significant separation from placebo in the primary efficacy measure” which Plaintiffs contend caused Forest’s stock price to plummet \$4.64. (See Amended Complaint ¶ 121.) On or about June 29, 2004, Forest disclosed that “the New York state attorney general’s office requested any information the company may have about off-label clinical trials and product promotions,” which Plaintiffs contend caused Forest’s stock to fall from approximately \$60 “to as low as \$54.97.” (Amended Complaint ¶¶ 125-126, 128.)

(3) Promotion of Off-Label Uses of Celexa/Lexapro for Children and Adolescents

The Amended Complaint also alleges that Forest impermissibly promoted its antidepressants for use by adolescents because “Forest’s executives knew that if they could get physicians to prescribe [Celexa and Lexapro] for childhood and adolescent depression, this would materially increase Forest’s revenues and profits.” (Amended Complaint ¶ 4.) The Amended Complaint contends, among other things, that at regional, quarterly “plan-of-action meetings . . . sales reps were given a script for informing doctors that Celexa and Lexapro were safe for children and adolescents.” (Amended Complaint ¶ 45.)

This promotion of Celexa and Lexapro for off-label uses allegedly made the following statement, from a July 2003 letter from Defendant Solomon to investors, false and misleading: “Marketing our products requires us to scrupulously inform physicians about those products. We are constantly communicating with physicians, but it must always be accurate and in ways that ultimately serve their patients’ interests. Above all, it is incumbent on us not to abuse our access to physicians

in ways that compromise their responsibility to their patients.” (Amended Complaint ¶ 81.)

Plaintiffs contend that Forest’s stock price began to drop from its Class Period high of \$77.70 on January 26, 2004, after Forest disclosed on January 29, 2004 that it had received a subpoena from the United States Attorney’s office in Philadelphia relating to the “potentially over-aggressive marketing of psychiatric drugs” and after “[a] scientific advisory panel urged the Food and Drug Administration . . . to issue stronger warnings to doctors . . . about the possible risks to children” presented by drugs such as Celexa and Lexapro. (Amended Complaint ¶¶ 104-106.) According to the Amended Complaint, Forest’s stock price dropped to as low as \$36.10 when Forest issued a press released on September 7, 2004 announcing “that it [would] establish a publicly available, on-line Clinical Trial Registry containing summaries of key Forest-sponsored clinical studies completed since January 1, 2000 for drugs which Forest currently markets . . . As a result of Forest’s adoption of the Clinical Trial Registry, the Attorney General has agreed to end his inquiry of Forest’s clinical study disclosure practices.” (Amended Complaint ¶¶ 30, 133.)

(4) Timing of Namenda FDA Approval Application

Plaintiffs contend that Forest misled the market with respect to Namenda, a drug approved by the FDA on or about October 17, 2003 for the treatment of moderate to severe Alzheimer’s disease, by making the following statements:

- “Forest Laboratories Inc. announced that results of a U.S. . . . study of Namenda . . . in mild to moderate Alzheimer’s disease shows the drug demonstrated a statically significant difference versus placebo with respect to the study’s primary efficacy measures of cognition and global outcome Forest plans to seek approval for a mild to moderate indication based on the positive outcome of the U.S. study” according to a Forest press release, dated January 7, 2004, entitled “Forest Laboratories to Seek Approval for Mild to Moderate Indication by Mid-Year.” (Amended Complaint ¶ 93.)
- Forest “reported a positive study outcome for our mild to moderate monotherapy study for Namenda which will support a supplemental New Drug Application for that indication around the middle of the year . . . [the] [t]rials are done. We basically just have to put the package together for all of the trials that have been done from mild to moderate and file that and that’s probably a six month process

to get that filing done” according to Defendant Goodman during a call with investors on or about January 20, 2004. (Amended Complaint ¶ 101.)

- “Based on the positive results of this study, Forest Laboratories plans to submit to the U.S. Food and Drug Administration a supplemental New Drug Application for a mild to moderate Alzheimer’s disease indication for Namenda by mid-2004” in a February 23, 2004 press release. (Amended Complaint ¶ 107.)
- “We anticipate submitting a supplemental New Drug Application for mild to moderate Alzheimer’s disease late this summer” according to Defendant Goodman during a conference call with investors on or about April 20, 2004. (Amended Complaint ¶ 112.)

Plaintiffs allege that these statements, among others, were false and misleading because “by mid-04, Forest had not filed the [application] and thus . . . Namenda would not be approved for active marketing or sale for use in patients with mild/moderate Alzheimer’s disease, at least not in the timeframe that Forest had previously indicated.” (Amended Complaint ¶ 136.) On July 26, 2005, “the FDA issued a non-approvable letter to Forest, denying its application to expand the approved uses of Namenda to include moderate-to-severe Alzheimer’s, confirming that the study it submitted to the FDA was never as conclusive as defendants represented.” (Amended Complaint ¶ 136.)

Plaintiffs claim that throughout the Class Period, the Individual Defendants sold more than five million shares of Forest stock, for more than \$300 million in profits. (See Amended Complaint ¶ 137.) Allegedly, Solomon sold 37% of his shares during the Class Period, for approximately \$221 million; Eggers sold 59% of his shares for more than \$4 million; Goodman sold 11% of his holdings for more than \$24 million; Hochberg sold 73% of her shares for more than \$12 million; Olanoff sold 69% of his shares for in excess of \$23 million; Prehn sold 88% of his holdings for more than \$4 million in proceeds; Stafford sold 50% of his holdings for more than \$9 million; and Triano sold 100% of his holdings during the Class Period for approximately \$1.5 million. (See Amended Complaint ¶ 137.)

Plaintiffs allege that these stock sales were executed, among other times, in late 2002 as Forest “publicized the success of Celexa and Lexapro in treating pediatric depression without adverse

side effects [and] successfully introduced Lexapro and was persuading physicians to switch large numbers of patients from Celexa to Lexapro due to its purported superior efficacy in treating depression,” so that Forest “officers and directors took advantage of the increasing artificial inflation in the price of the stock by bailing out.” (Amended Complaint ¶ 17.)

III. Legal Standard

In resolving a motion to dismiss, the Court “must accept the factual allegations of the complaint as true and must draw all reasonable inferences in favor of the plaintiff.” Bernheim v. Litt, 79 F.3d 318, 321 (2d Cir. 1996). “The issue is not whether a plaintiff is likely to prevail ultimately, ‘but whether the claimant is entitled to offer evidence to support the claims.’” Gant v. Wallingford Bd. of Educ., 69 F.3d 669, 673 (2d Cir. 1995) (citation omitted). In considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a district court limits consideration “to the factual allegations in plaintiffs’ [complaint], . . . to documents attached to the complaint as an exhibit, or incorporated in it by reference, to matters of which judicial notice may be taken, or to documents either in plaintiffs’ possession or of which plaintiffs had knowledge and relied on in bringing suit.” Brass v. Am. Film Techs., Inc., 987 F.2d 142, 150 (2d Cir. 1993); see also Cortec Indus., Inc. v. Sum Holding L.P., 949 F.2d 42, 48 (2d Cir. 1991).

To state a claim under § 10(b) and Rule 10b-5, a plaintiff “must plead that the defendant, in connection with the purchase or sale of securities, made a materially false statement or omitted a material fact, with scienter, and that the plaintiff’s reliance on the defendant’s action caused injury to the plaintiff.” Ganino v. Citizens Utils. Co., 228 F.3d 154, 161 (2d Cir. 2000); see Dura Pharm., Inc. v. Broudo, 125 S.Ct. 1627, 1631 (2005) (basic elements of Section 10(b) claim are “(1) a material misrepresentation (or omission);” “(2) scienter;” “(3) a connection with the purchase or sale of a security;” “(4) reliance;” “(5) economic loss;” and “(6) ‘loss causation’”) (emphasis omitted). Where plaintiffs allege fraud, “the circumstances constituting fraud . . . shall be stated with particularity.”

Fed. R. Civ. P. 9(b); see Stern v. Gen. Elec. Co., 924 F.2d 472, 476 (2d Cir. 1991). Defendants must be afforded “a reasonable opportunity to answer the complaint and . . . adequate information to frame a response.” Ryan v. Hunton & Williams, No. 99 Civ. 5938, 2000 WL 1375265, at *6 (E.D.N.Y. Sept. 20, 2000).

IV. Analysis

(A) Alleged False and Misleading Statements

Defendants argue that the Amended Complaint “fails to allege specific facts and to identify sources or documents indicating why any Defendant’s statement was materially misleading when made.” (Def. Mem. at 11.) Defendants also contend that “[b]ecause Plaintiffs do not attribute any allegedly misleading statements to Defendants Hochberg, Olanoff, Prehn, and Stafford, or allege their participation in such statements, the § 10(b) claims against these Individual Defendants must be dismissed.” (Def. Mem. at 10.) Plaintiffs counter that the Amended Complaint “easily meets” the pleading standards of the PSLRA and Rule 9(b), (Pl. Mem. at 10), and that Hochberg, Olanoff, Prehn, and Stafford are “top executives at Forest” and “this Court has previously affirmed the ‘group pleading doctrine,’” which presumes that statements in a company’s documents are the work of its officers and directors. (Pl. Mem. at 22.)

The Private Securities Litigation Reform Act of 1995 (“PSLRA”) requires that a complaint “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” Novak v. Kasaks, 216 F.3d 300, 306 (2d Cir. 2000); see 15 U.S.C. § 78u-4(b)(1); see In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 69-70 (2d Cir. 2001) (“The complaint must identify the statements plaintiff asserts were fraudulent and why, in plaintiff’s view, they were fraudulent, specifying who made them, and where and when they were made.”).

Characterization of Celexa/Lexapro

Plaintiffs contend that, throughout the Class Period, Defendants repeatedly represented to investors that Lexapro was different from and superior to Celexa. (See Amended Complaint ¶ 53 (Lexapro has “greater effect, faster speed of action and fewer side effects” than Celexa.); Amended Complaint ¶ 62 (“Lexapro “is quite different So, for patients we will have a drug that is more efficacious, acts more quickly, has lower side effects and has less drug interaction than [Celexa].”).) Plaintiffs contend that these statements were false based upon the Danish Medicines Agency, the Center for Medicare & Medicaid Services within the United States Department of Health and Human Services, and an independent study in the medical journal Psychotherapy and Psychosomatics, which “found that claims of Lexapro’s superiority were unfounded.” (Pl. Mem. at 19.) These allegations are sufficient to plead a false or misleading statement under § 10(b). Scholastic, 252 F. 3d at 69; see In re Quintel Entertainment Inc. Sec. Litig., 72 F. Supp. 2d 283, 293 (S.D.N.Y. 1999).

Concealment of Unfavorable Celexa/Lexapro Studies

Plaintiffs contend that Defendants misled investors by publishing clinical data favorable to Celexa while concealing unfavorable data. (See, e.g., Amended Complaint ¶ 13 (“In publicizing its two short, small and purportedly successful Celexa/Lexapro pediatric use studies in 12/01, 5/02, 7/02, 9/02 and 12/02 and then using them to improperly promote Celexa/Lexapro for ‘off-label’ use, Forest was concealing from physicians, patients, parents, financial markets and even Forest’s own salesforce that, during 96-02, Lundbeck, the developer and licensor of Celexa/Lexapro to Forest, had conducted a large, six-year study of Celexa’s efficacy and safety involving over 422 children and adolescents which had demonstrated that there was no pre-adult efficacy from the drug and – worse yet – that there were significant adverse side-effects, including increased suicidality.”).) If ultimately proven, these publications may be actionable under Section 10(b). See Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 357 (2d Cir. 2002) (“The touchstone of the inquiry is not whether isolated statements

within a document were true, but whether defendants' representations or omissions, considered together and in context, would affect the total mix of information and thereby mislead a reasonable investor regarding the nature of the securities offered."); see also In re Regeneron Pharm. Sec. Litig., No. 94 Civ. 1785, 1995 WL 228336, *3 (S.D.N.Y. March 10, 1995).

Promotion of Off-Label Uses of Celexa/Lexapro for Children and Adolescents

Plaintiffs allege that Forest's off-label promotion rendered the following statement false and misleading: "Marketing our products requires us to scrupulously inform physicians about those products. We are constantly communicating with physicians, but it must always be accurate and in ways that ultimately serve their patients' interests. Above all, it is incumbent on us not to abuse our access to physicians in ways that compromise their responsibility to their patients." (Amended Complaint ¶ 81.) Concealment of the fact that Forest's sales force (allegedly) improperly promoted Celexa for off-label uses may be misleading. See United Paperworkers Int'l v. Paper Co., 801 F. Supp. 1134, 1143 (S.D.N.Y. 1992) ("[S]ince the [company] chose to offer specific representations about [its] environmental record and policies, it was obligated to portray that record fairly."); In re Providian Fin. Corp. Sec. Litig., 152 F. Supp. 2d 814, 825 (E.D. Pa. 2001) ("Were [Defendant] engaged in a series of illegal or fraudulent business practices and were those practices responsible for inflating revenue, profit, and the customer base, such information would clearly alter the mix of information available to the public as to the source of Providian's success"); see also Roeder v. Alpha Indus., Inc., 814 F.2d 22, 25 (1st Cir. 1987) ("Management's willingness to engage in practices that probably or obviously are illegal, and its decision to put the corporation at risk by so doing, may be critically important factors to investors. Investors may prefer to steer away from an enterprise that circumvents fair competitive bidding and opens itself to accusations of misconduct. Furthermore, regardless of financial motives, investors may not want to associate themselves with such an enterprise.") (internal citations omitted).

Timing of Namenda FDA Approval Application

Plaintiffs unpersuasively allege that statements regarding Defendants' application for approval of Namenda for use in patients displaying mild to moderate Alzheimer's symptoms were false and misleading. The statements cited by Plaintiffs were predictions about when a Namenda approval application might be filed and did not guarantee that Namenda would ultimately be approved by the FDA for use in treating this category of Alzheimer's patients. (See, e.g., Amended Complaint ¶ 107 ("Based on the positive results of this study, Forest Laboratories plans to submit to the U.S. Food and Drug Administration a supplemental New Drug Application for a mild to moderate Alzheimer's disease indication for Namenda by mid-2004.") (emphasis added); Amended Complaint ¶ 94 ("Forest's unexpected announcement that Namenda, which had failed an earlier mild/moderate Alzheimer's disease test, had now proved efficacious for this purpose and thus, according to Forest, would likely be approved for treatment for all stages of Alzheimer's disease in a reasonably short timeframe") (emphasis added).) These statements do not support Plaintiffs' Section 10(b) claim because any reasonable investor would know that the timing of the Namenda application was subject to change and that Forest could not guarantee that the application would ultimately be approved. See In re Bristol-Myers Squibb Sec. Litig., 312 F.Supp.2d 549, 558 (S.D.N.Y. 2004) ("Any reasonable investor reading these statements, or any of the other statements regarding [an FDA approval application] . . . would recognize that the Defendants could not and did not guarantee that [the drug] would be approved by the FDA, either in the near term or at all. Statements such as these are plainly opinions, not guarantees, and are not actionable.") (internal citations omitted); see also In re Int'l Bus. Machines Corporate Sec. Litig., 163 F.3d 102, 107 (2d Cir. 1998) ("[Defendants'] management lacked the actual or apparent authority to guarantee [a] dividend, and it would be unreasonable for the market to have interpreted the statements at issue as anything other than an individual's prediction about the future. Accordingly, we conclude that the challenged statements are, as a matter of law,

opinions and not guarantees.”).

Group Pleading Doctrine

Defendants contend that Hochberg, Olanoff, Prehn, and Stafford should be dismissed because “Plaintiffs do not attribute any allegedly misleading statements to [these Defendants] or allege their participation in such statements.” (Def. Mem. at 10.) Plaintiffs respond that these Defendants “as top executives at Forest, are liable for the Company’s statements even if they made no statements personally.” (Pl. Mem. at 22.) Plaintiffs are persuasive at this stage because these Defendants are alleged to have had direct involvement in Forest’s every day business in their capacities as Forest’s Senior Vice President for Marketing, Executive Vice President of Scientific Affairs, Vice President of Licensing and Corporate Development, and Vice President of Global Marketing, respectively. (See Amended Complaint ¶ 40 (“The Individual Defendants were Forest’s eight top executive officers charged with not only developing Forest’s business strategy, but also overseeing the implementation and execution of that strategy during the Class Period.”)); In re Solv-Ex Corp. Sec. Litig., 210 F. Supp. 2d 276, 283 (S.D.N.Y. 2000) (“Under the group pleading doctrine, Plaintiffs may rely on a presumption that statements in prospectuses, registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company. No specific connection between fraudulent representations in a published company document is necessary where defendants are insiders or affiliates of the company.”) (internal citations omitted).

(B) Knowledge/Scienter

Defendants argue, among other things, that “Plaintiffs have neither . . . pled strong circumstantial evidence of any Defendant’s scienter nor . . . created a strong inference of any Defendant’s ‘motive’ by making incomplete and misleading assertions about the Individual Defendants’ stock transactions over a two-year putative class period.” (Def. Mem. at 19.) Plaintiffs

respond that “Defendants knowingly and recklessly misrepresented Forest’s products and practices, sold huge amounts of their own stock, then left innocent investors holding the bag when the truth came out.” (Pl. Mem. at 3.)

A plaintiff can establish a “strong inference” of scienter by alleging: (1) facts constituting “strong circumstantial evidence of conscious misbehavior or recklessness,” or (2) facts showing that defendants had “both motive and opportunity to commit fraud.” Rothman v. Gregor, 220 F.3d 81, 90 (2d Cir. 2000); Shields v. Citytrust Bancorp, 25 F.3d 1124, 1128 (2d Cir. 1994). “To qualify as reckless conduct, defendants’ conduct must have been highly unreasonable and an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” Scholastic, 252 F.3d at 76; In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36, 39 (2d Cir. 2000) (“To survive dismissal under the ‘conscious misbehavior’ theory, [a plaintiff] must show that the alleged reckless conduct by [defendant] . . . was either known to the defendant or so obvious that the defendant must have been aware of it.”)

Plaintiffs have properly pleaded Defendants’ knowledge with respect to the characterizations of Lexapro/Celexa, concealment of unfavorable Lexapro/Celexa studies, and the off-label promotion of Celexa/Lexapro for use in treating child and adolescent depression because they have alleged circumstantial evidence of conscious misbehavior and because they have alleged Defendants’ motive and opportunity.⁴

Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

Defendants argue that “the general allegation that Defendants ‘had actual knowledge of the misrepresentations and omissions of material facts’ . . . is insufficient.” (Def. Mem. at 19.) Plaintiffs contend, among other things, that Defendants “were provided with unpublished, unfavorable Celexa

⁴ The Court need not decide whether Plaintiffs properly pleaded scienter with respect to the Namenda claim since that claim has been dismissed.

studies during the Class Period but suppressed them” and “personally attended annual sales meetings in Orlando, Florida, where Forest sales representatives were instructed to illegally promote Forest drugs for unapproved uses.” (Pl. Mem. at 2.) Plaintiffs also contend that Defendants’ “positions as the highest-ranking executives at Forest are sufficient on their own to raise a strong inference that defendants were informed about the Company’s most important products.” (Pl. Mem. at 2.)

“Although this is a highly fact-based inquiry, the Second Circuit has held that where the complaint alleges that defendants had knowledge of facts or access to information contradicting their public statements, recklessness has been adequately pled.” In re Mercator Software, Inc. Sec. Litig., 161 F. Supp. 2d 143, 149 (D. Conn. 2001) (citing Carter-Wallace, 220 F.3d at 39). “Where plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information.” Novak, 216 F.3d at 309; see San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 812 (2d Cir. 1996).

With respect to the alleged misleading characterizations of Celexa and Lexapro as different from one another, knowledge of (the similarities and differences between) Celexa and Lexapro goes to Forest’s core business operations and is, therefore, presumed by Defendants. See In re Atlas Air Worldwide Holdings, Inc. Sec. Litig., 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004) (“When a plaintiff has adequately alleged that the defendant made false or misleading statements, the fact that those statements concerned the core operations of the company supports the inference that the defendant knew or should have known the statements were false when made. Indeed, if facts that contradict a high-level officer’s public statements were available when the statements were made, it is reasonable to conclude that the speaker had intimate knowledge of those facts or should have known of them.”).

With respect to the efficacy and safety of Celexa and Lexapro in children and adolescents, Plaintiffs allege that Defendants had knowledge of unfavorable studies. (See Amended Complaint ¶ 12 (“during the Class Period, while Forest was proclaiming and publicizing the success of its

Celexa/Lexapro transition and the success of the new Lexapro drug to the financial community, it was illegally promoting Celexa/Lexapro for 'off-label' childhood/adolescent use and concealing its own study data (as well as other data available to it) that indicated that SSRI anti-depressant drugs (including Celexa/Lexapro) did not work in children/adolescents and were associated with increased suicidality in that population.") Among other things, Plaintiffs point to a New York Times report, dated June 21, 2004, in which a "spokesman for Lundbeck said the company reported the [unpublished Lundbeck Study] trial results to Forest." (Amended Complaint ¶ 117.) And, Plaintiffs (correctly) contend that the suicide warnings on Lundbeck's European version of Celexa put Forest on notice of the risks of suicide associated with Celexa and Lexapro. (See Pl. Mem. at 14 (Defendants "were on notice that Lundbeck had concerns regarding Celexa's safety because Lundbeck had sold Celexa in Denmark for many years with a label warning of possible suicide risks. As such, defendants had an obligation to request and review any relevant safety and efficacy data from Lundbeck before representing to investors that it was purportedly safe.")); Novak, 216 F.3d at 308 ("we have found allegations of recklessness to be sufficient where plaintiffs alleged facts demonstrating that defendants failed to review or check information that they had a duty to monitor.").

With respect to the off-label promotion of Celexa and Lexapro for use by children and adolescents, Plaintiffs allege that Defendants knowingly promoted these drugs for unapproved, off-label uses. (See, e.g., Amended Complaint ¶ 46 ("Sales reps were given a script for informing doctors that Celexa and Lexapro were safe for children and adolescents"); Amended Complaint ¶ 47 ("Forest sales reps were commonly provided with copies and instructed to distribute journal articles for studies conducted by other companies for drugs in the same class, such as other SSRIs, for promotion of Celexa/Lexapro. As described above, the subject of the studies conducted by other companies were for indications that had not been approved by the FDA for Forest's product.")); see

In re Initial Public Offering Sec. Litig., 241 F. Supp. 2d 281, 382 (S.D.N.Y. 2003) (“participants in the securities markets are entitled to presume that all of the actors are behaving legally; silence that conceals illegal activity is therefore intrinsically misleading and (presuming the illegality is also material) is always violative of Rule 10b-5(b).”). The Amended Complaint includes details of where and when this information was reviewed by Defendants. (See, e.g., Amended Complaint ¶ 44 (“At the annual sales meeting in Orlando ... Goodman and ... Solomon attended with the entire team of nationwide sales reps. Goodman and Solomon spoke to the team and provided an overview of the sales training focus. The theme was sometimes conveyed by showing slides with pictures of an internist or a child psychiatrist and then commenting that . . . the child psychiatrist is not writing enough prescriptions for Celexa or Lexapro. Sales reps then separated into groups of 40 or so in order to begin the training portion of this meeting.”)); see Mercator, 161 F.Supp.2d at 150. And, when Forest stated “marketing products requires us to scrupulously inform physicians about those products” and “not to abuse our access to physicians,” it was obligated to disclose the results of all studies about which it had knowledge. United Paperworkers, 801 F. Supp. at 1143 (“[S]ince the [company] chose to offer specific representations about [its] environmental record and policies, it was obligated to portray that record fairly.”).

Motive and Opportunity

Defendants argue that “the class period transactions were neither unusual nor in any way suspicious.” (Def. Mem. at 22.) Plaintiffs contend that the Individual Defendants’ (extensive) stock sales during the Class Period give rise to a strong inference of scienter. (See Pl. Mem. at 22.)

“The motive and opportunity element is generally met when corporate insiders misrepresent material facts to keep the price of stock high while selling their own shares at a profit.” Scholastic, 252 F.3d at 74-75 (internal citations omitted). “Unusual insider sales at the time of the alleged withholding of negative corporate news may permit an inference of bad faith and scienter.”

Scholastic, 252 F.3d at 74-75 (internal citations omitted). “Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling.” Scholastic, 252 F.3d at 74-75 (internal citations omitted).

The Amended Complaint alleges that the Individual Defendants sold an “unusual” amount of shares, see Scholastic, 252 F.3d at 74-75, i.e. more than five million shares of Forest Stock for more than \$300 million in profits. (See Amended Complaint ¶ 137.) These stock sales, executed during the Class Period by eight “corporate insiders,” support a strong inference of fraudulent intent. See Stevelman v. Alias Research Inc., 174 F.3d 79, 85-86 (2d Cir. 1999) (“Perhaps the most persuasive allegation in the Amended Complaint is the fact that . . . Alias officers, sold off large portions of his stockholdings during the period of the misrepresentations . . . [I]t is probative of motive, which we have recognized supports a strong inference of fraudulent intent. The allegation supports the inference that [Defendant] withheld disclosures that would depress his stock until he had profitably sold his shares.”) Defendants’ sales are “unusual.” See In re Oxford Health Plans, Inc., 187 F.R.D. 133, 140 (S.D.N.Y. 1999) (“There is no guide for determining whether certain insider trades are unusual or suspicious in amount. Large volume trades may be suspicious but where a corporate insider sells only a small fraction of his or her shares in the corporation, the inference of scienter is weakened. The \$78 million profit from sales by the Individual Defendants during the Class Period is, however, massive by any measure.”) (internal citation omitted).

(C) Loss Causation

Defendants argue that “particular facts, not broad conclusions, are required to plead loss causation” and that Plaintiffs’ have failed to allege such facts. (Def. Mem. at 27.) Plaintiffs counter that the Amended Complaint “identifies defendants’ false and misleading statements . . . sets forth the disclosures which alerted the market to the false and misleading nature of defendants’ statements . . .

and the subsequent declines in Forest's stock price as the artificial inflation created by defendants' misrepresentations dissipated." (Pl. Mem. at 28.)

"Loss causation 'is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.'" Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005) (quoting Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc., 343 F.3d 189, 197 (2d Cir. 2003)). Under the PSLRA, Plaintiffs must "adequately allege a causal connection between defendants' non-disclosures and the subsequent decline in the value of [the security]." Emergent Capital, 343 F.3d at 197; see also 15 U.S.C. § 78u-4(b)(4) ("In any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages."). "[T]o establish loss causation, 'a plaintiff must allege . . . that the subject of the fraudulent statement or omission was the cause of the actual loss suffered' . . . i.e., that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." Lentell, 396 F.3d at 173 (emphasis in original) (citations omitted). "[L]oss causation has to do with the relationship between the plaintiff's investment loss and the information misstated or concealed by the defendant If that relationship is sufficiently direct, loss causation is established." Lentell, 396 F.3d at 174 (internal quotations and citations omitted).

The Amended Complaint fails to allege adequately a causal link between the allegedly improper comparisons of Lexapro and Celexa and the fall in stock price in 2004. See In re QLT Inc. Sec. Litig., 312 F. Supp. 2d 526, 536 (S.D.N.Y. 2004). That is, Plaintiffs have not pointed to any specific announcement or corrective disclosure with respect to the Celexa/Lexapro comparisons, nor have they pointed to any specific stock price reaction due to these comparisons. See id.⁵

⁵ Even if the Court had not previously dismissed Plaintiffs' claims regarding the filing of Forest's approval application with the FDA for Namenda, this claim would nonetheless be dismissed because Plaintiffs have failed to allege any causal link between statements about the FDA application

Plaintiffs do adequately allege loss causation for the two remaining claims, i.e. that Forest concealed unfavorable studies of Celexa and Lexapro and that Forest improperly promoted those drugs for use in children and adolescents. Lentell, 396 F.3d at 174. That is, Plaintiffs allege that Forest's stock price dropped when facts about the allegedly concealed Lundbeck Study were reported on June 21, 2004 and on June 28, 2004. (See Amended Complaint ¶ 118 (on June 21, 2004, "Forest's stock continued to decline in light of this adverse publicity."); Amended Complaint ¶ 123 ("Forest's stock price continued to fall as low as \$57.10 on 6/28/04 as more artificial inflation came out of the stock, as more truth entered the market.")) Plaintiffs also allege that Forest's stock price dropped when The New York Times published its June 30, 2004 report that the New York Attorney General was investigating Forest's alleged off-label promotions. (See Amended Complaint ¶ 128 ("Forest's stock fell to as low as \$54.97, as further artificial price inflation came out of the stock.")).

(D) Control Person Liability

Defendants argue that Section 20(a) claims can not be sustained because Plaintiffs have not sufficiently alleged a Section 10(b) violation. (See Def. Mem. at 29.) Plaintiffs contend that the Section 10(b) claims are sufficient to justify the Section 20(a) claims. (See Pl. Mem. at 30.)

Section 20(a) of the Exchange Act imposes joint and several liability on any person who "controls any person liable under any provision of this title or any rule or regulation thereunder." Ruskin v. TIG Holdings, Inc., No. 98 Civ. 1068, 2000 WL 1154278, at *7 (S.D.N.Y. Aug. 14, 2000); see 15 U.S.C. § 78t(a). A plaintiff must show: (i) a primary violation of Section 10(b) by the controlled person; (ii) control of the primary violator by the defendant; and (iii) "that the controlling person was in some meaningful sense a culpable participant." S.E.C. v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996).

Plaintiffs' Section 20(a) claims survive because the Amended Complaint properly pleads

and the fall in Forest's stock price. See In re QLT Inc. Sec. Litig., 312 F. Supp. 2d 526, 536 (S.D.N.Y. 2004).

violations of Section 10(b). The Court is not dismissing Plaintiffs' Section 20(a) claims relating to the alleged failure to disclose studies about the safety and efficacy of Celexa and Lexapro as well as the improper off-label promotion of those drugs to children and adolescents. See, e.g., In re Sterling Foster & Co. Sec. Litig., 222 F. Supp. 2d 216, 277, 282-23 (E.D.N.Y. 2002) (denying motion to dismiss Section 20(a) claim where Section 10(b) claim survives); see also Scholastic, 252 F.3d at 78; Buxbaum v. Deutsche Bank, A.G., No. 98 Civ. 8460, 2000 WL 33912712, at *19 (S.D.N.Y. Mar. 7, 2000); In re Credit Suisse First Boston Corp. Sec. Litig., No. 97 Civ. 4760, 1998 WL 734365, at *12 (S.D.N.Y. Oct. 20, 1998).

(E) Leave to Amend

Plaintiffs request that, if the Court determines that there are any deficiencies in the Amended Complaint, they be given leave to amend pursuant to Fed. R. Civ. P. 15(a). (Pl. Mem. at 30 n.19.) Defendants do not address whether Plaintiffs should be granted leave to replead.

Fed. R. Civ. P. 15(a) provides that leave to amend the complaint "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a); Panio v. Beverly Enters., Inc., No. 86 Civ. 6422, 1990 WL 41767, at *2 (S.D.N.Y. Apr. 4, 1990). Leave to amend should especially be granted "[i]n the absence of undue . . . delay, bad faith or dilatory motive on the part of the movant," or "undue prejudice to the opposing party," Foman v. Davis, 371 U.S. 178, 182 (1962), and "where dismissal of the complaint was based on Rule 9(b)." Acito v. IMECERA Group, Inc., 47 F.3d 47, 55 (2d Cir. 1995); see also Dovitz v. Rare Medium Group, Inc., No. 01 Civ. 10196, 2002 WL 1225540, at *5 (S.D.N.Y. June 4, 2002). Plaintiffs are granted leave to file a Second Amended Complaint on or before August 28, 2006.

IV. Conclusion and Order

For the reasons stated herein, Defendants' Motion to Dismiss [#32] is granted in part and denied in part. Plaintiffs have properly pleaded claims with respect to Forest's alleged failure to

disclose studies about the safety and efficacy of Celexa and Lexapro as well as the improper off-label promotion of those drugs to children and adolescents. Plaintiffs' claims relating to alleged improper characterizations of Lexapro as different from Celexa and the timing of a potential Namenda approval application are dismissed without prejudice.

The parties are directed to appear at a status/settlement conference on September 18, 2006 at 11:30 a.m., in Courtroom 14A of the United States Courthouse, 500 Pearl Street, New York, New York, 10007. **The Court directs the parties to engage in good faith settlement negotiations prior to the conference with the Court.**

Dated: New York, New York
July 19, 2006



Richard M. Berman, U.S.D.J.

**Counsel receiving this documentation
is directed forthwith to transmit a copy
to all other counsel/parties in these
proceedings and to retain proof of
such transmittal.**

Richard M. Berman, U.S.D.J.